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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
IMPROVED FLUID SAMPLING APPARATUS					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number 25213 OR <input type="checkbox"/> Firm or Individual Name		Type Customer Number here → Place Customer Number Bar Code Label here			
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages 9		<input type="checkbox"/> CD(s), Number 			
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<input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		FILING FEE AMOUNT (\$)			
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Date **06/11/2003**
 REGISTRATION NO. **43,209**
 (if appropriate)
 Docket Number: **38187-2599**

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Attorney Docket No.: 38187-2599

PROVISIONAL PATENT APPLICATION
IMPROVED FLUID SAMPLING APPARATUS

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IMPROVED FLUID SAMPLING APPARATUS

5

BACKGROUND OF THE INVENTION

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

10 Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet.

15 Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major

20 impediment to patient compliance with a structured glucose monitoring regime.

Success rate generally encompasses the probability of producing a blood sample with one lancing action, which is sufficient in volume to perform the desired analytical test. The blood may appear spontaneously at the surface of the skin, or may be "milked" from the wound. Milking generally involves pressing the side of the digit, or in proximity of the wound to express the blood to the surface. In traditional methods, the blood droplet produced by the lancing action must reach the surface of the skin to be viable for testing.

When using existing methods, blood often flows from the cut blood vessels but is then trapped below the surface of the skin, forming a hematoma. In other instances, a wound is created, but no blood flows from the wound. In either case, the lancing process cannot be combined with the sample acquisition and testing step. Spontaneous blood droplet generation with current mechanical launching system varies between launcher types but on average it is about 50% of lancet strikes, which would be spontaneous.

30

Otherwise milking is required to yield blood. Mechanical launchers are unlikely to provide the means for integrated sample acquisition and testing if one out of every two strikes does not yield a spontaneous blood sample.

Many diabetic patients (insulin dependent) are required to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing ranging from lancing, to milking of blood, applying blood to the test strip, and getting the measurements from the test strip discourages many diabetic patients from testing their blood glucose levels as often as recommended. Tight control of plasma glucose through frequent testing is therefore mandatory for disease management. The pain associated with each lancing event further discourages patients from testing. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

Another problem frequently encountered by patients who must use lancing equipment to obtain and analyze blood samples is the amount of manual dexterity and hand-eye coordination required to properly operate the lancing and sample testing equipment due to retinopathies and neuropathies particularly, severe in elderly diabetic patients. For those patients, operating existing lancet and sample testing equipment can be a challenge. Once a blood droplet is created, that droplet must then be guided into a receiving channel of a small test strip or the like. If the sample placement on the strip is unsuccessful, repetition of the entire procedure including re-lancing the skin to obtain a new blood droplet is necessary.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved fluid sampling device. Intelligent control of the velocity profile of the penetrating member will increase the likelihood of spontaneous blood generation. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one aspect of the present invention, the invention relates to using the electronic tissue penetration device to drive a penetrating member into the skin to a predetermined depth

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

5 DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to
10 diameter or length, than those of conventional penetrating members known in the art. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

15 It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include
20 mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

25 "Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the
30 analysis feature and structures wherein the analysis feature is not present.

Referring now to Figure 1, a plurality of conventional fluid sampling and specifically, glucose spot monitoring devices are shown. As a nonlimiting example, the one step solution of the present invention may combine the steps 1-7 into a single process

to the user. In one embodiment, this may comprise pressing a single button to lance and obtain a blood glucose or other analyte reading. In other embodiments, the one step may be augmented by a step using a slider (see Figure 4) that is movable to load a new unused penetrating member in active position. In some embodiments, this may involve rotating the cartridge (see Figure 4) to bring the member into alignment with the penetrating member coupler.

Referring now to Figure 2, shows the evolution of integrated fluid sampling and monitoring devices. As seen, adaptive control may be added to a fluid sampling device to provide improved control of penetrating member depth. Adaptive control may involve an algorithm in the device controller which may take input from the user such as but not limited whether blood was spontaneously generated, pain level, sufficient blood generation, time of day during lancing, hydration of the user, location selected for lancing, or like from a lancing event. The algorithm will take these at least one of these variables and adjust the next lancing event to optimize lancing performance. Adjustments may include, but are not limited to, increasing or decreasing desired depth, adjusting velocity profile, changing braking force, changing coasting time, adjusting for tenting of tissue, or the like. It should be understood that other adjustments to penetrating member performance may be made to improve spontaneous blood generation or to reduce user pain.

Referring now to Figure 3, an image is shown where a device 100 according to the present invention may be designed to replace a plurality of conventional elements shown on the left of the figure.

Referring now to Figure 4, one embodiment of an improved fluid sampling device 100 is shown. The device 100 includes a display 102, a penetrating member actuation button 104, adjustment buttons 106 and 108, and a front end annular ring 110. In this embodiment, a slider 112 is movable as indicated by arrow 114. A pop-open button 116 is provided and is movable as indicated by 118. This opens the device 100 as shown in Figure 6. This embodiment of device 100 may also include a see-through window 120 that allows a user to see a cartridge inside the device 100. It should be understood that this window 120 may be provided in a variety of shapes including the U-shaped configuration shown in Figure 4, a full circular window, a U-shaped window on the top portion or mirror-imaged upward from the configuration shown in Figure 4, comprise of a

plurality of smaller windows, or otherwise configured or positioned to show a user that a cartridge is inside the device.

Referring now to Figure 5, close-up view is shown of the front end annular ring 110. The cartridge 130 with a sterility barrier can be seen through the front end. It should be understood that in some embodiments, the portion 132 of the housing having the front end annular ring 110 may be removed to allow the entire annular ring 110 to be replaced either for cleaning purposes or for removal in its entirety.

Referring now to Figure 6, a portion of the interior of the device 100 is shown with the bottom portion 140 being opened. A battery compartment 142 is provided to house a power source for this embodiment of the device 100.

Referring now to Figure 7A, the embodiment of device 100 is shown with the underside 140 hinged open. A battery 144 is shown in the compartment 142. The cartridge 130 is rotatable as indicated by arrow 146. It should be understood, of course, that the cartridge 130 may be designed to rotate in a counterclockwise direction in another embodiment. A rotatable gear 150 (shown more clearly in Figure 11) that is linked to slider 112, will rotate to rotate the cartridge 130. In the present embodiment, a support member 160 is provided to position the cartridge 130 in the areas where the penetrating member coupler 170 will engage the penetrating members. Although not limited to the following, the support member 160 is mounted on springs 162 which may allow the support to be moved downward and then urged back to its original position. In this embodiment as shown in Figure 7B, this allows the penetrating member coupler 170 to move downward in a longer stroke. The stroke length helps to ensure that the coupler 170 engages the penetrating member in the cartridge 130. The support member 160 and the entire cartridge 130 may be moved downward and upward as indicated by arrows 172. The maximum downward position of the cartridge 130 and the support member 160 is shown in phantom. In the present embodiment, the support member 160 is positioned to not interfere with the rotation of the cartridge 130 but allows the cartridge 130 be sufficiently supported and positioned in place to allow a penetrating member coupler to accurately engage the cartridge 130 and a penetrating member held therein.

Referring now to Figure 8, a close-up top down view is shown of an embodiment of a cartridge 130 according to the present invention. As seen in Figure 8, the inner circumference may include a notch 180 to facilitate positioning and/or rotation of the cartridge 130. The cartridge 130 may also include gear teeth 182 to engage a

corresponding gear on the gear 150 shown in Figure 11. As seen in the Figure 8, the cartridge 130 may include a park portion 184 to hold a penetrating member 186 in the cartridge. The rear bearing 188 will, in this embodiment, remain in guide contact with the penetrating member 186 so that the penetrating member does not stray while it is being
5 actuated.

Figures 9 and 10 show various features of embodiments of the improved fluid sampling device 100.

Referring now to Figure 11, a close-up view is shown of the components used to engage and actuate a penetrating member. A penetrating member coupler 170 is shown
10 along with a punch 190 used to open a sterility barrier covering the cartridge 130 and keeping the penetrating member in a sterile condition prior to use. Further details on the function of the coupler 170 and punch 190 are discussed in U.S. Patent Application Attorney Docket No. 38187-2606. Gear 150 will rotate to increment the cartridge 130 as desired. Movement of the gear 150 may be coupled to a slider 112.

15 Referring now to Figure 12, a top view of an embodiment of the device 100 is shown with the top of the device removed and showing the electronics.

Referring now to Figure 13, the following shows the time it may take to obtain a fluid sample and provide a reading. In one embodiment of the present invention, the device may provide a time of less than about 20 seconds using an electronic lancing
20 device. The method may also be one that uses actuation based on a single button. Improved embodiments such as GM1 and GM2 as seen in U.S. Patent Application Attorney Docket No. 38187-2662 fully incorporated herein by reference may provide total times of less than about 15 seconds and less than about 10 seconds.

Referring now to Figures 14 and 15, the pain associated with the embodiment of
25 device 100 will have initial pain and residual pain levels significant lower than those of conventional ballistic devices.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention.

5 For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating
10 members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The
15 penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some
20 embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially
25 the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be
30 interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

- 1 1. A method of body fluid sampling comprising:
2 moving a penetrating member at conforming to a selectable velocity
3 profile or motion waveform;
4 achieving higher rates of spontaneous blood and higher spontaneous yields
5 by controlling depth of penetration.
- 1 2. The device of claim 1 wherein the penetrating member trajectory
2 waveform contains a stationary portion.
- 1 3. A device for body fluid sampling usable with a cartridge housing a
2 plurality of penetrating members, the device comprising:
3 a housing;
4 a penetrating member driver coupled to said housing and for use with said
5 cartridge;
6 a processor for controlling said penetrating member driver to move at least
7 one of said penetrating members at velocities which conform with a selectable velocity
8 profile.
- 1 4. The device of claim 3 comprising a window allowing a user to see
2 the cartridge while the cartridge is in said housing.
- 1 5. The device of claim 3 comprising display showing device status.
- 1 6. The device of claim 3 comprising display showing lancing
2 performance.
- 1 7. The device of claim 3 comprising display showing lancing
2 parameters.
- 1 8. The device of claim 3 comprising a single button for actuating said
2 penetrating member driver along an inbound path into tissue and then an outbound path
3 out of the tissue.

1 9. The device of claim 3 wherein said penetrating member driver
2 moves an active one of said penetrating members along a velocity profile that reduces
3 initial pain and residual pain to levels below that of known devices.

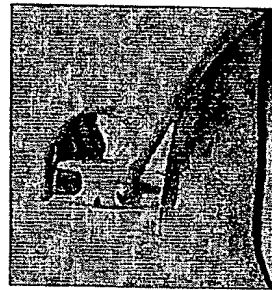
1 10. The device of claim 3 wherein said penetrating member driver
2 moves an active one of said penetrating members along a velocity profile that reduces
3 initial pain and residual pain to levels at least 1.5 times less than that of known devices.

1 11. The device of claim 3 wherein said penetrating member driver
2 moves an active one of said penetrating members along a velocity profile that reduces
3 residual pain to levels at least 2 times less than that of known devices.

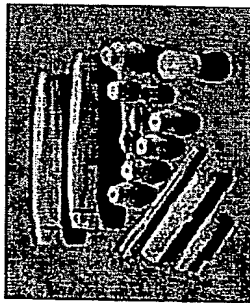
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Current paradigm of blood glucose monitoring vs. the Pelikan approach

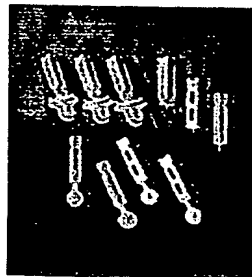
Current monitoring is a cumbersome process



Prick finger or arm



Load lancet into launcher and Reassemble launcher



Remove lancet protective cover



Deposit blood drop on to test strip



Read test strip

Today's Products Pelikan's One-Step Solution

1. Insert fresh lancet into device
 2. Prepare strip
 3. Lance finger
 4. Apply blood to strip
 5. Read results
 6. Dispose of lancet
 7. Dispose of strip
- Push one button and read result

Figure 1

Product Evolution of Step-Wise Integrating of Sampling and Measurement

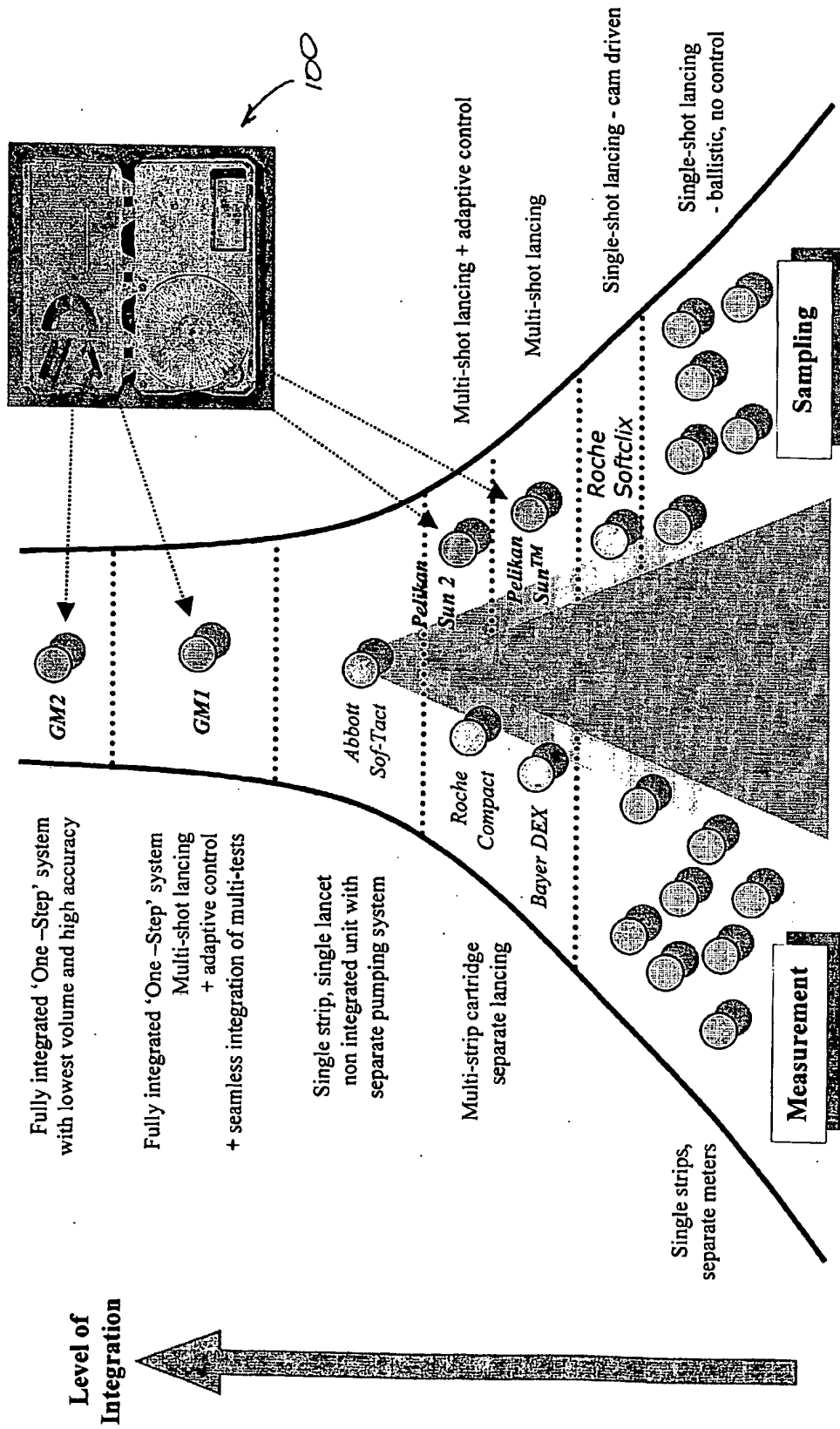


Figure 2

Pelikan offers one-step operation in a fully integrated system

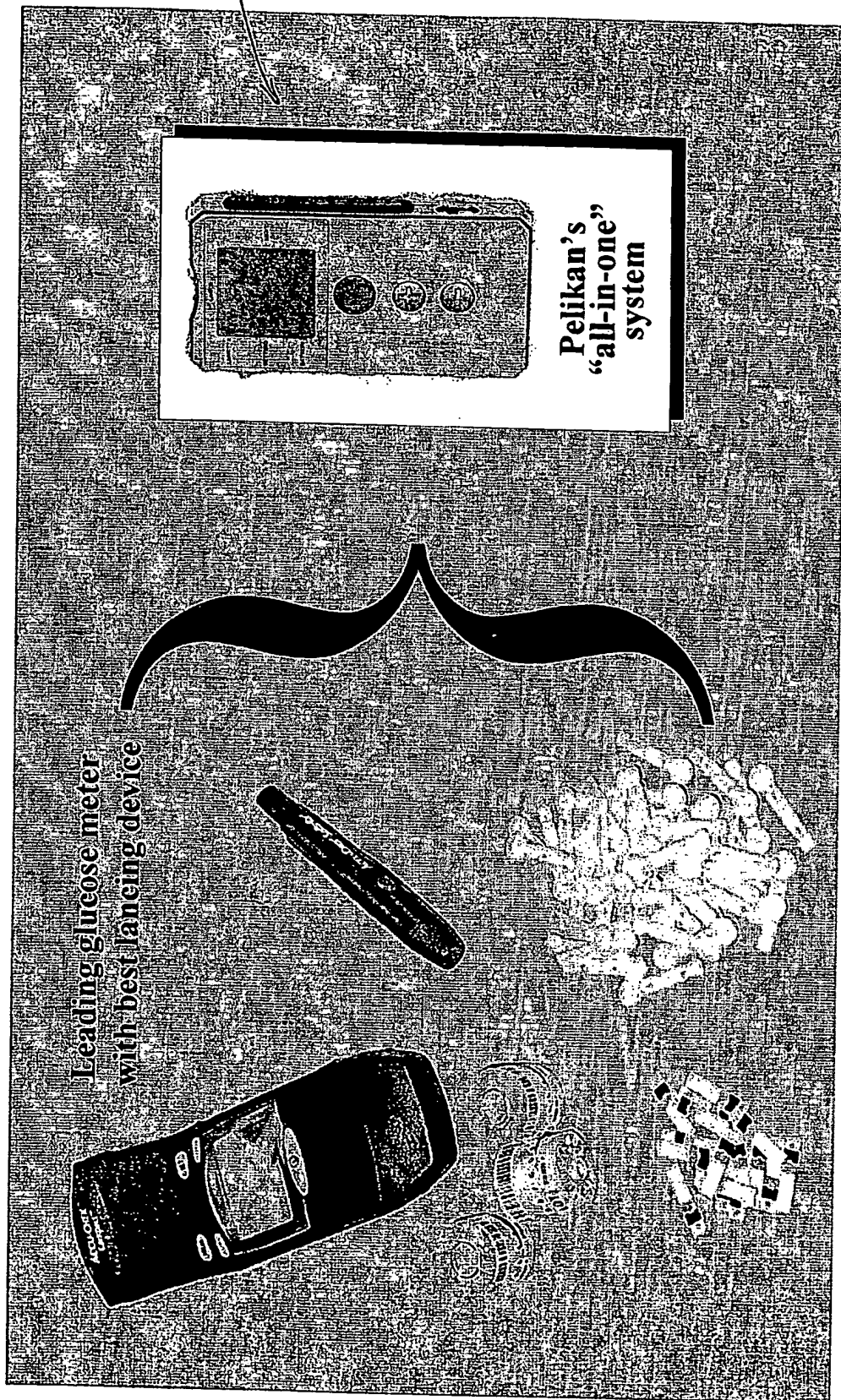


Figure 3

Pelikan form factor

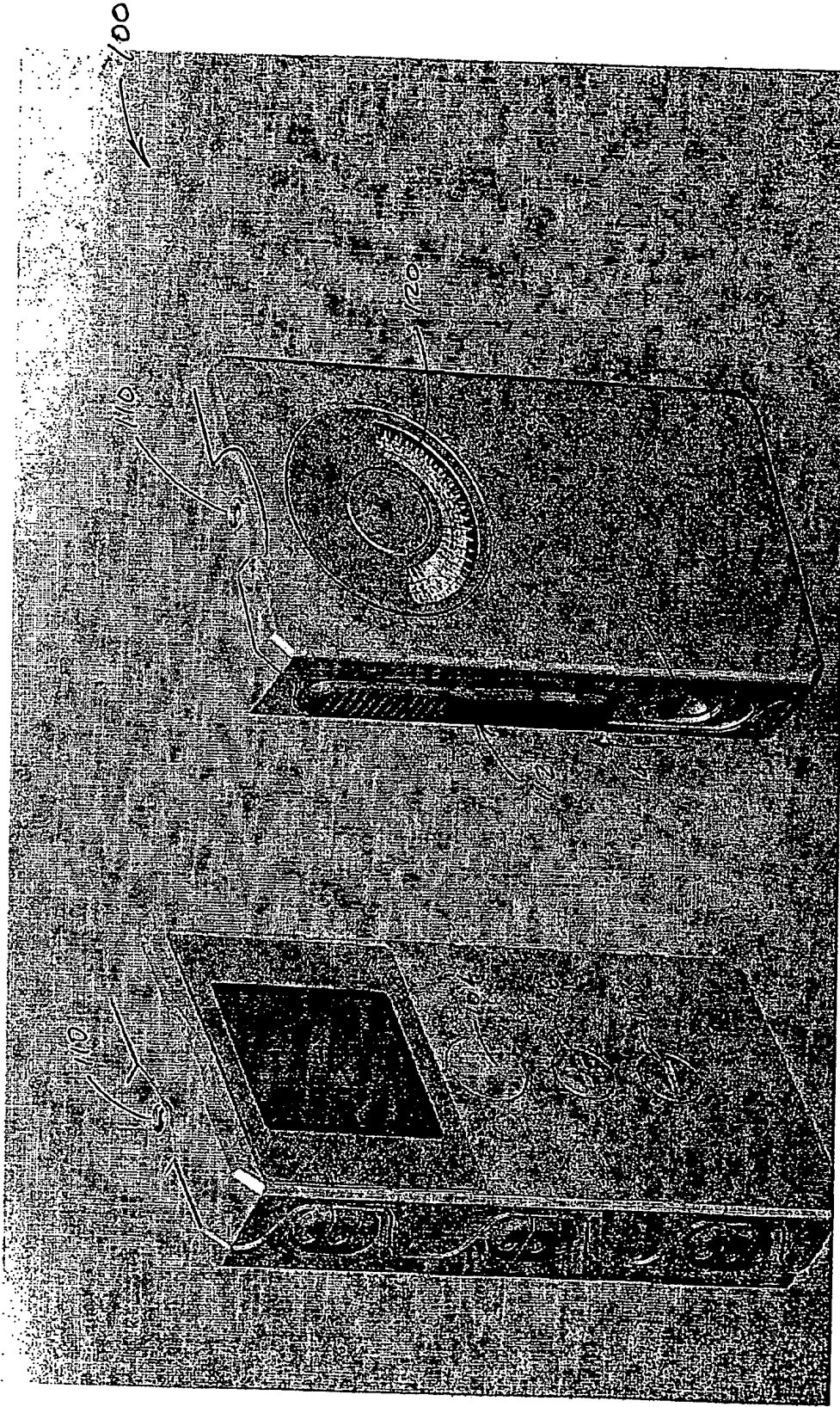


Figure 4

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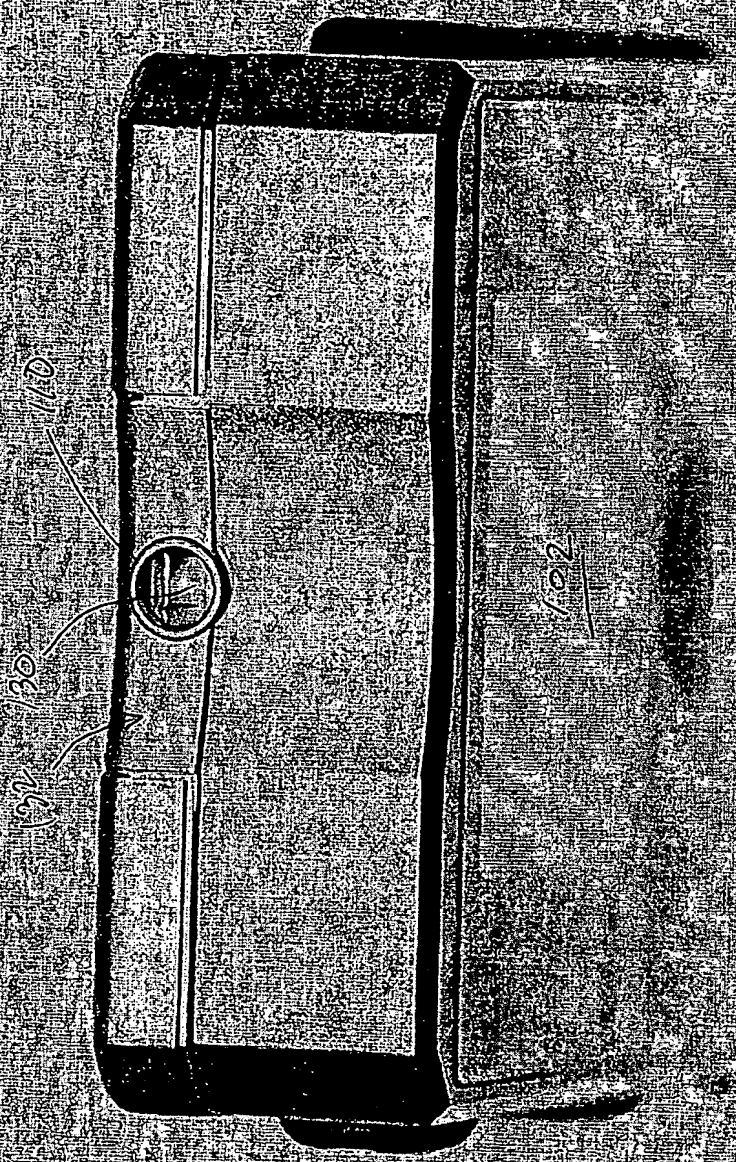


Figure 5

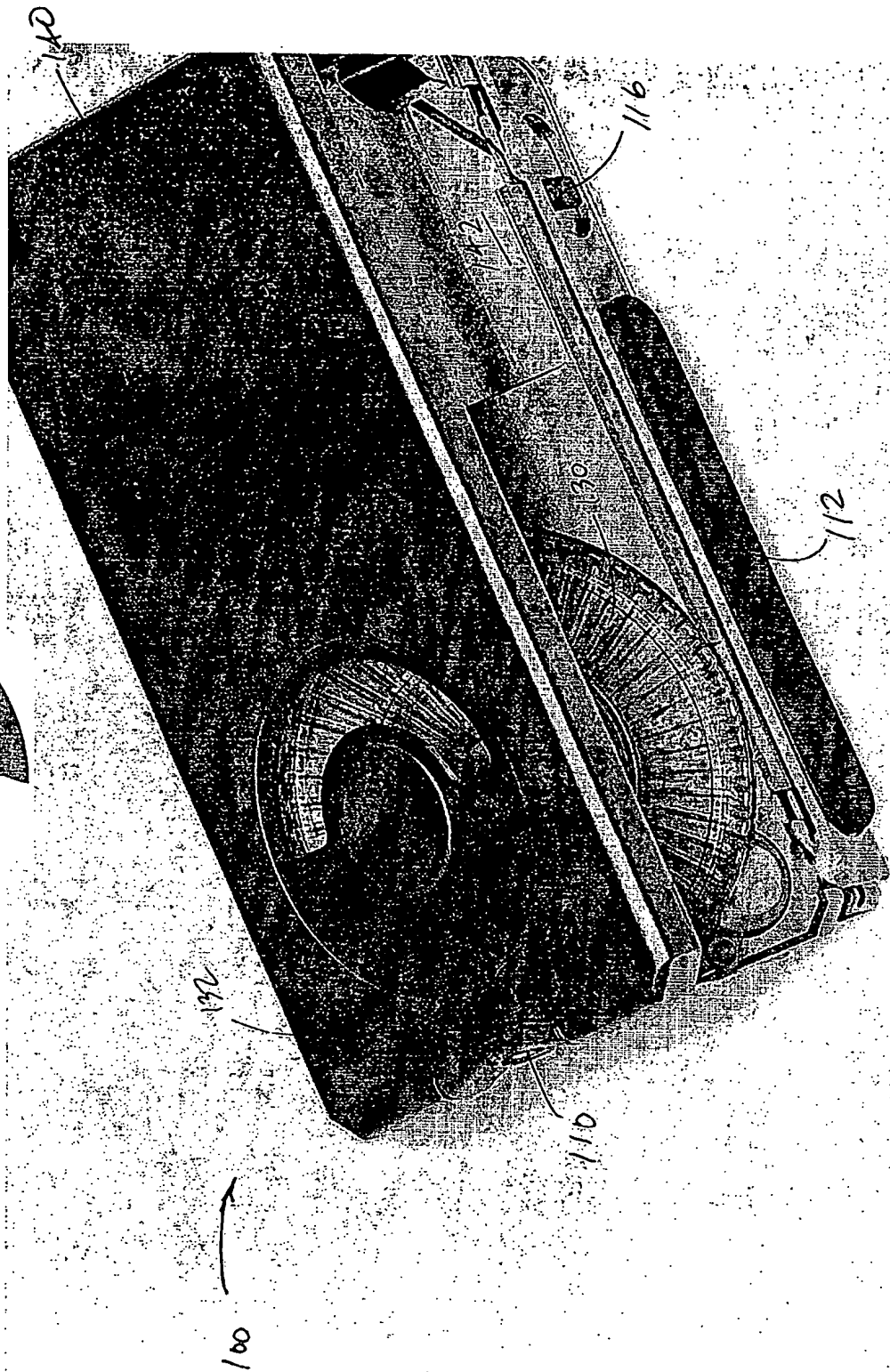


Figure 6

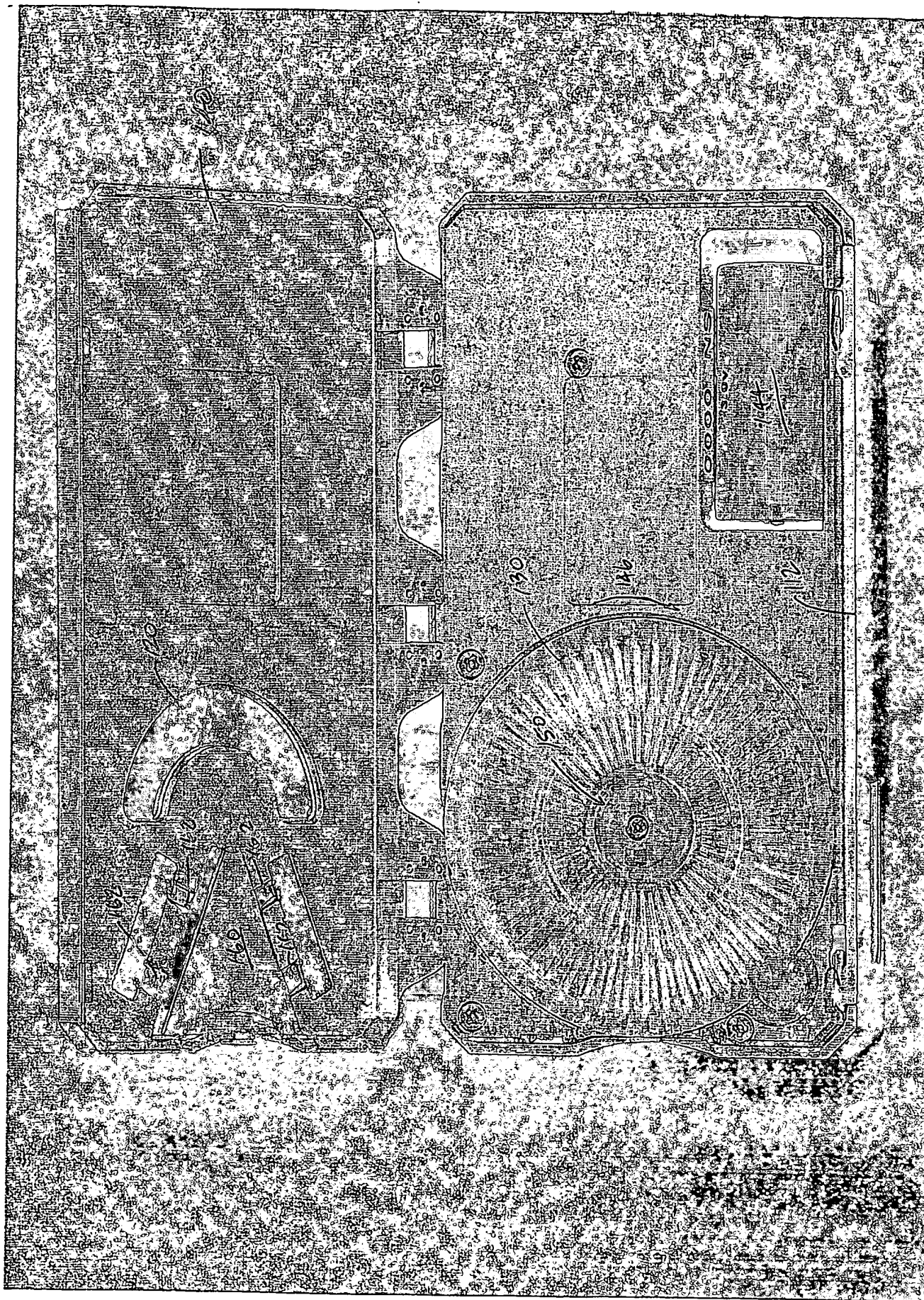


Figure 7A

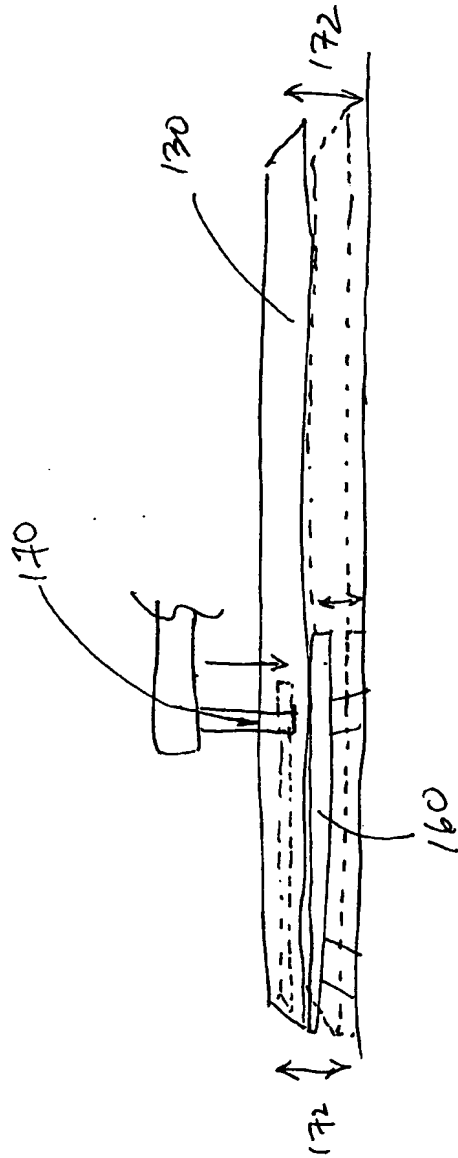


FIG-7B

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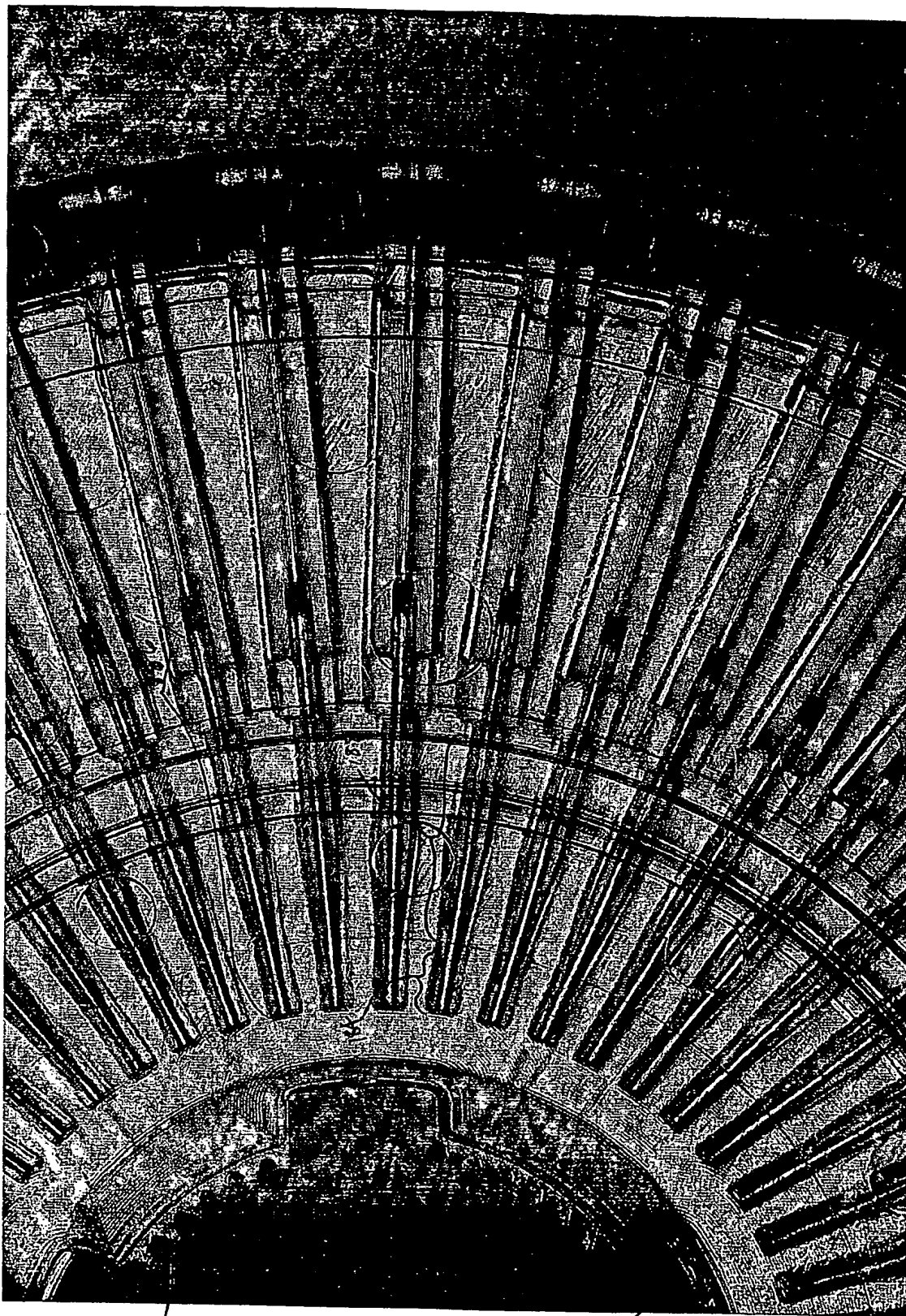


Figure 8

Pelikan can sample blood with less pain

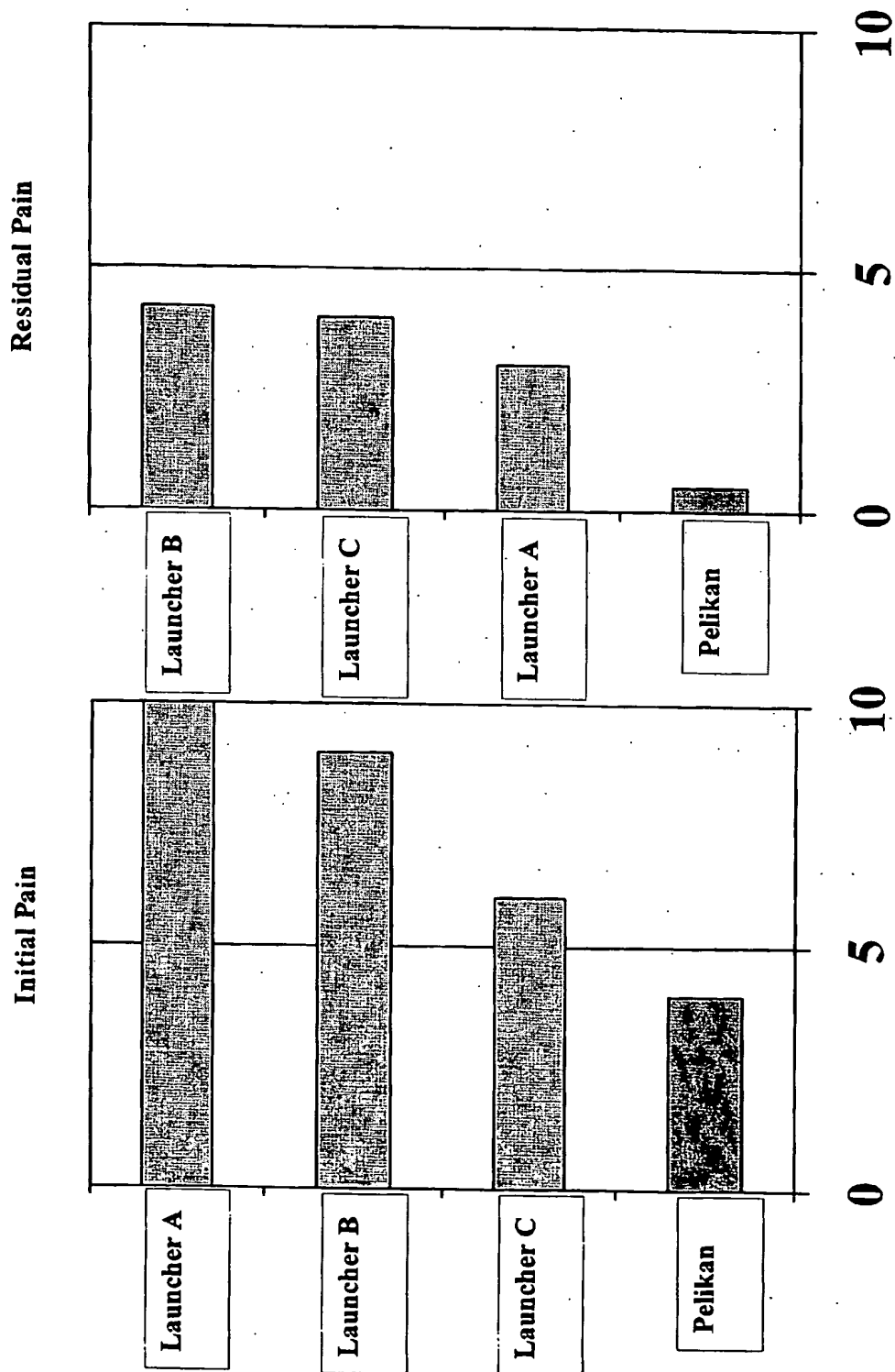


Figure 9

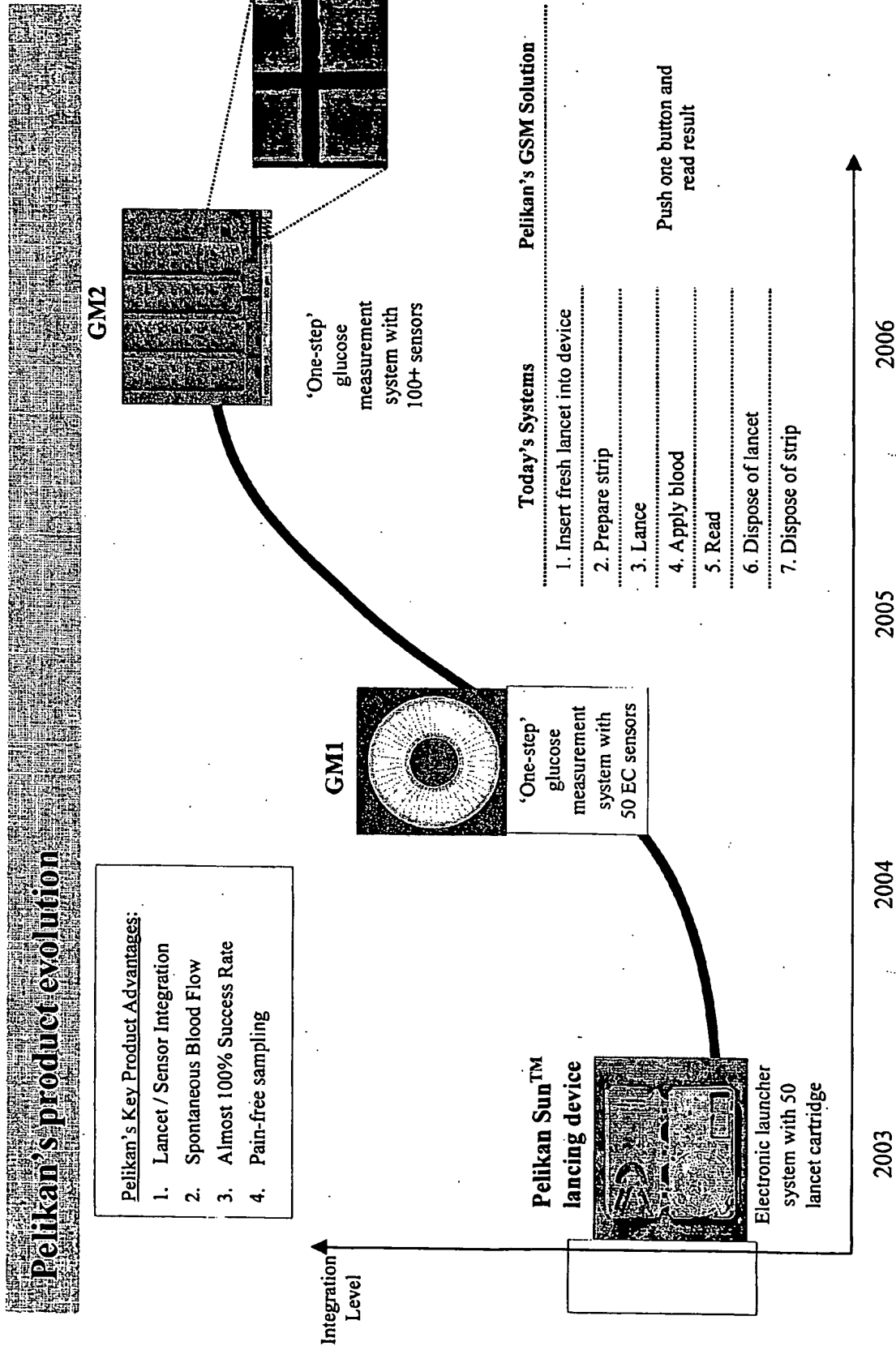


Figure 10

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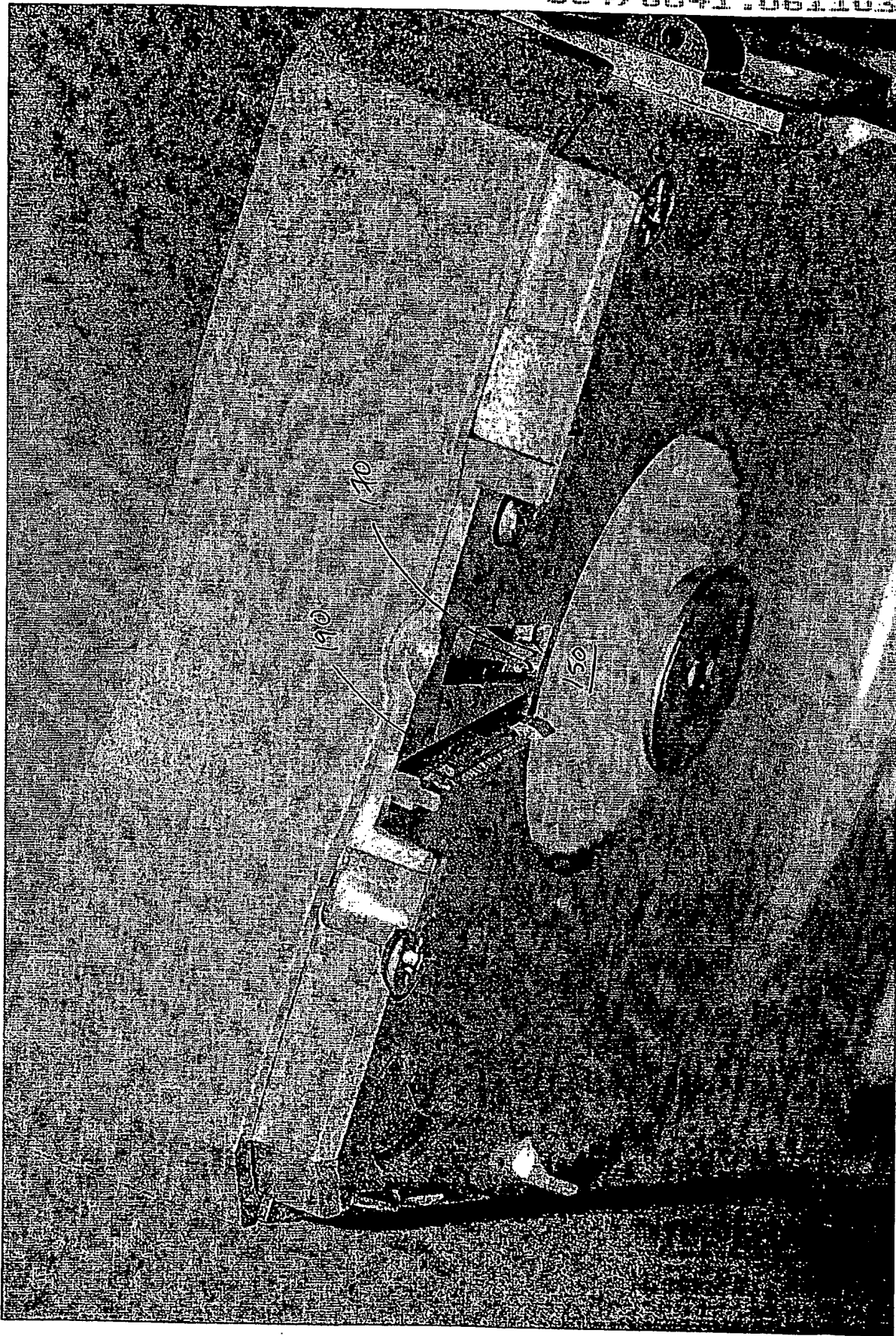
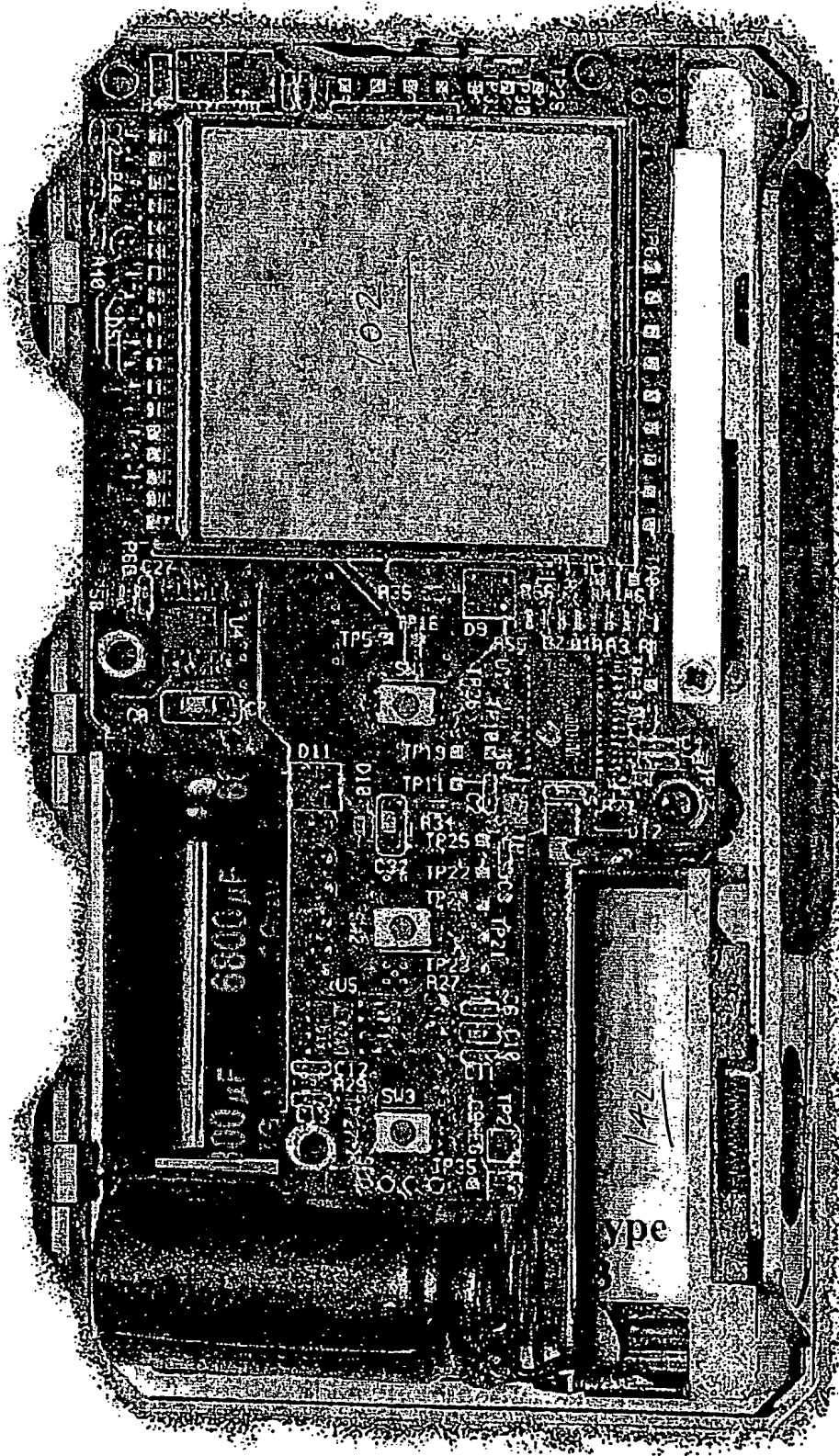


Figure 11

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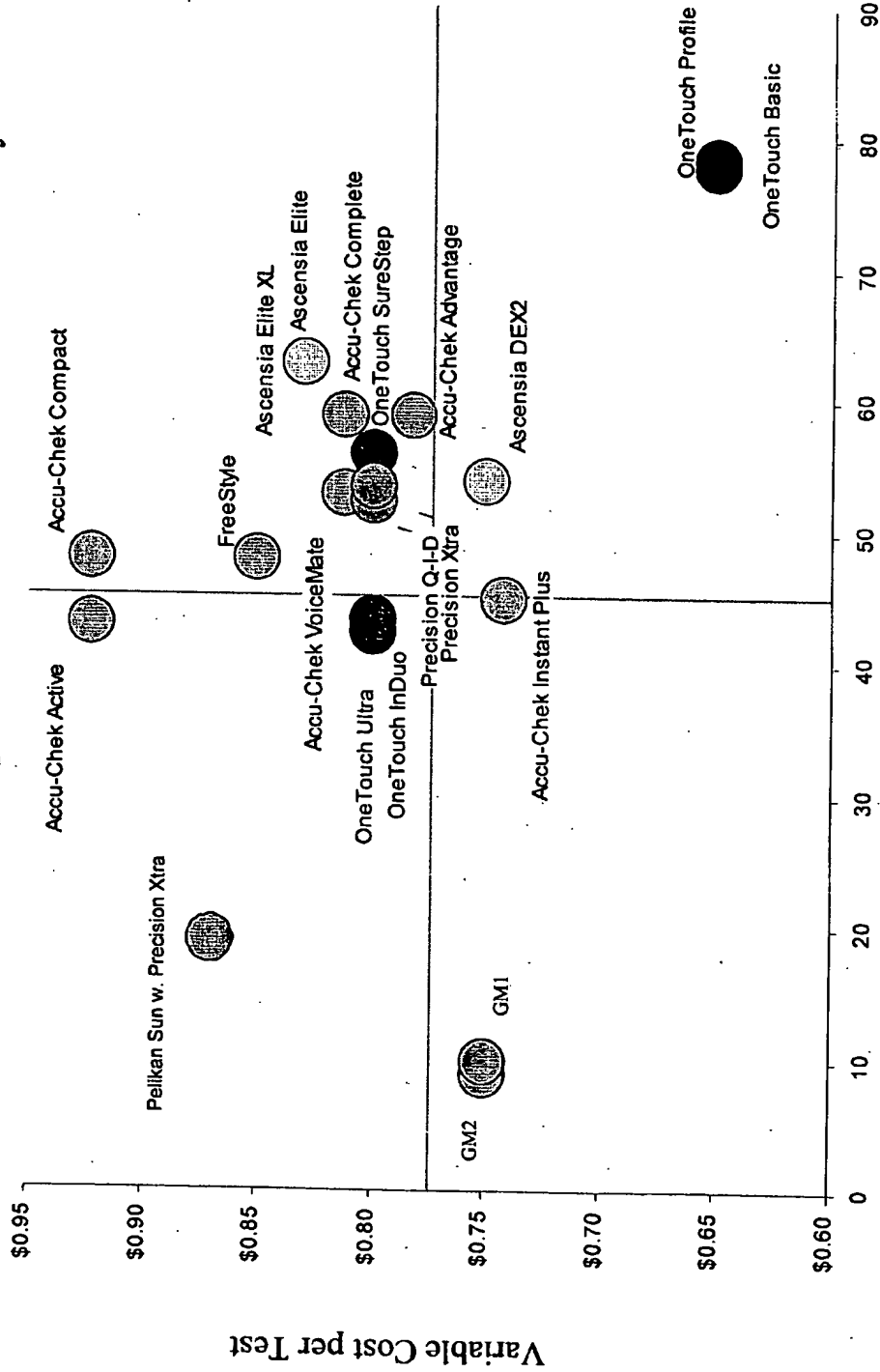
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Figure 12

type

Pelikan Products Will Shorten Test Time

Test Time and Cost per Test for Meters on the Market Today



Length of Test Procedure (sec.)

Figure 13

Pelikan's technology offers significant pain reduction

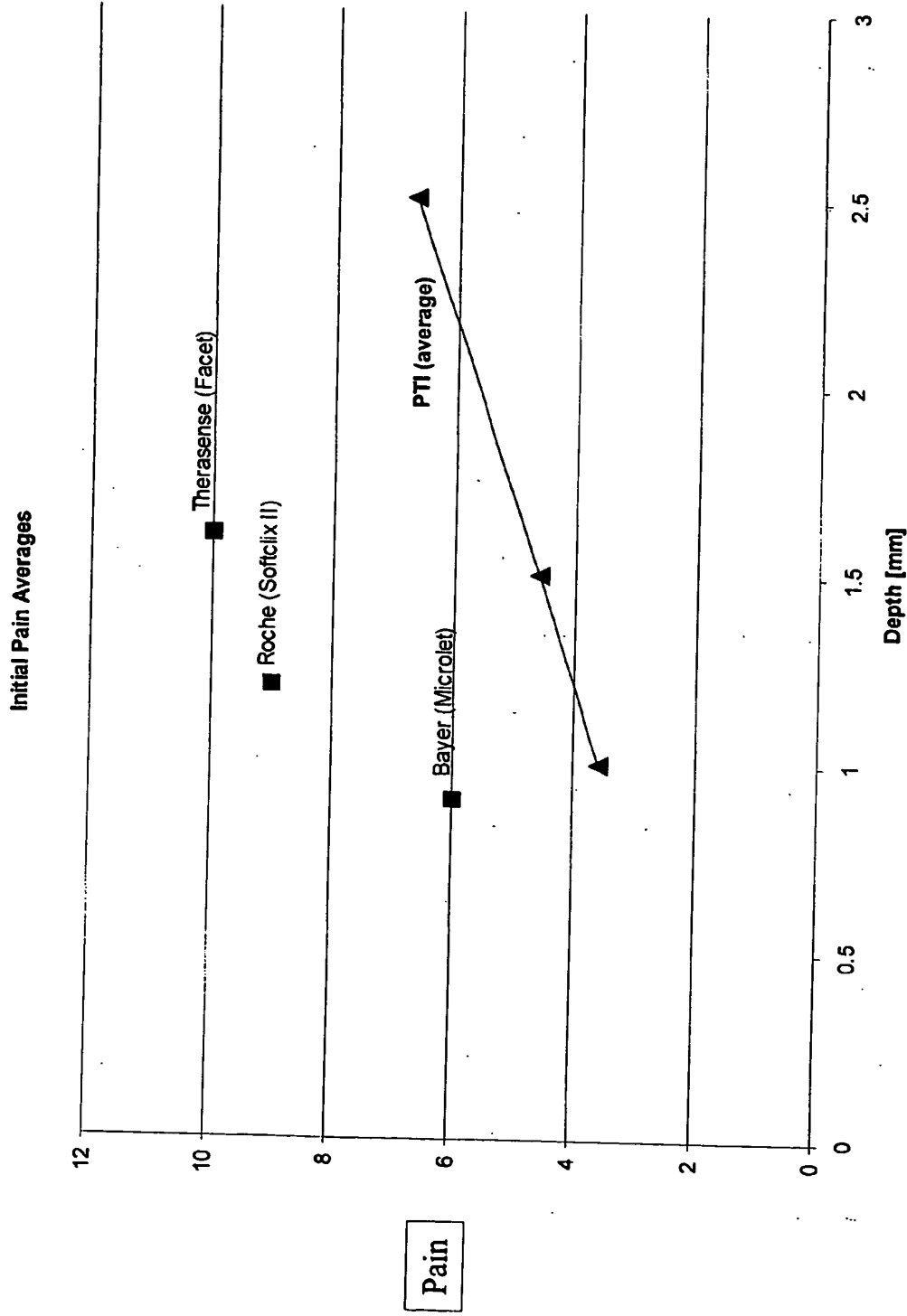


Figure 14

Pelikan's technology offers significant pain reduction

Residual Pain Averages

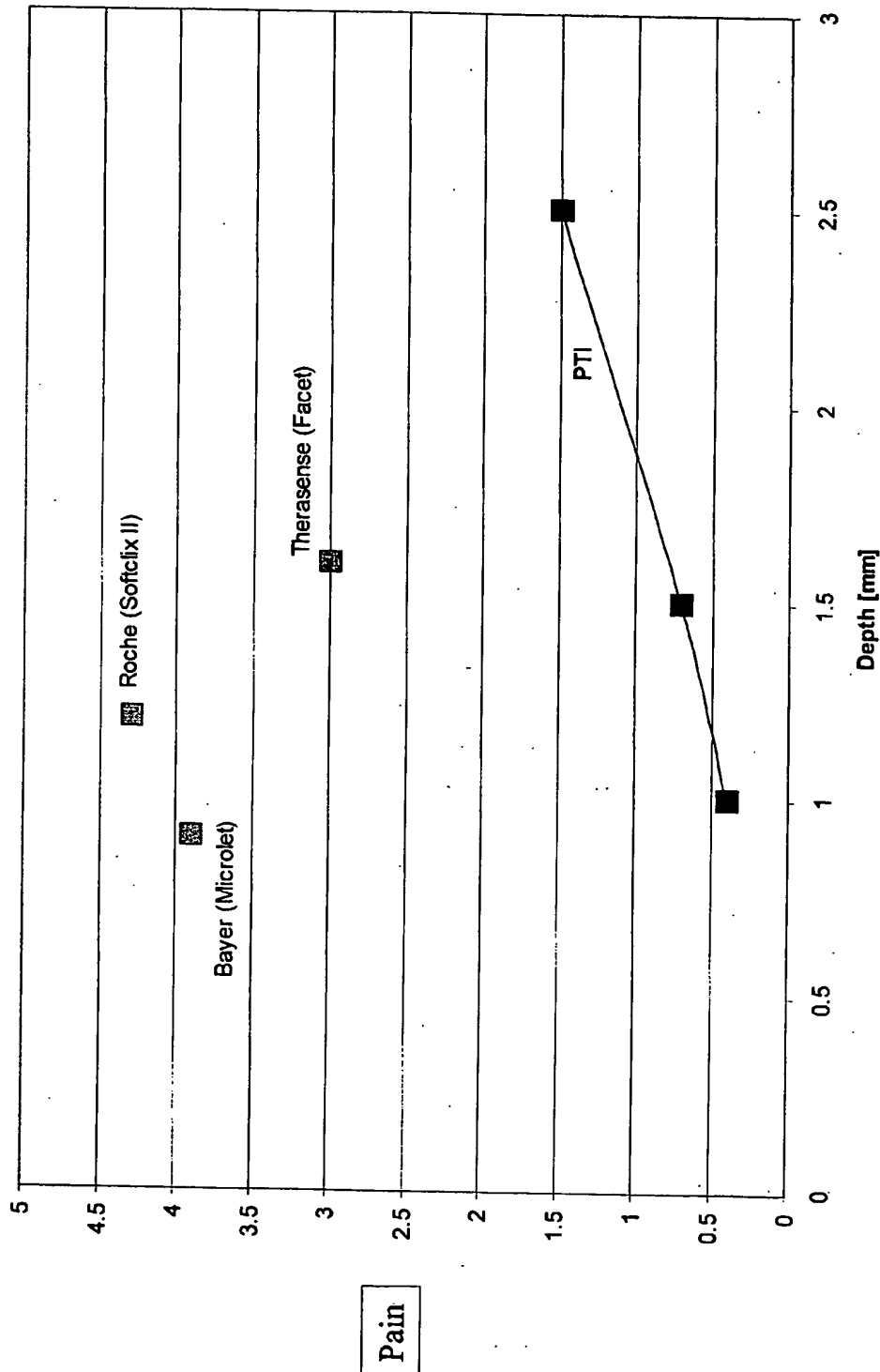


Figure 15

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